

REMARKS

The following remarks are responsive to the Office Action dated September 2, 2008 (hereinafter, "Office Action"). As discussed below, Claims 1-15 remain pending in the present application.

Claim Rejections – 35 U.S.C. 103:

Applicants submit that the Office Action fails to present a prima facie obviousness rejection because neither of the cited references disclose a self-expanding prosthesis. Applicants also submit that the Office Action fails to satisfy the required burden in establishing an obviousness rejection based, in part, on the requirements set forth in the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*

For example, as will be described in greater detail below, the proposed combinations involve several modifications and changes to the prior art. However, the Office Action fails to articulate specific rationales for the proposed combinations and modifications of the references, while also ignoring the whole teachings of the prior art references.

As discussed more fully below, there are significant differences between the cited references and the claimed devices of Claims 1-15 that do not appear to have been fully considered in reaching the conclusions set forth in the Office Action. Some of the distinctions between the cited references in the invention set forth in Claims 1-15, without limitation, are listed below, along with a discussion of the significance of these distinctions.

- U.S. Patent No. 5,769,885 ("Quiachon") discloses/suggests a deployment system for a balloon expandable prosthesis (i.e., not a self-expandable prosthesis), while Claims 1-15 are directed to deployment systems for self-expandable bifurcated prostheses.
- Further, the sheath disclosed/suggested in Quiachon is configured to cover the entire graft, while the deployment systems of Claims 1, 10 have three separate graft restraints/covers.
- U.S. Patent No. 5,647,857 ("Anderson") discloses/suggests a single sheath for use in a deployment system having an expandable balloon/expandable member positioned a tubular,

non-bifurcated stent/graft, while Claims 1-15 are directed to a self-expanding bifurcated graft/prosthesis.

- Further, the sheath disclosed/suggested in Anderson is configured to cover the entire non-bifurcated graft, while the deployment systems of Claims 1, 10 have three separate graft restraints/covers.

Rejection of Claims 1-15 under 35 U.S.C. 103(a):

Claims 1-15 stand rejected under 35 U.S.C. as being unpatentable over Quiachon in view of Anderson. For the reasons set forth herein, Applicants submit that one skilled in the art would not modify Quiachon's intraluminal grafting system as proposed by the Examiner in the Office Action. Additionally, even if modified in view of Anderson as suggested in the Office Action, Applicants submit that Quiachon's intraluminal grafting system would not disclose, suggest, or render obvious the bifurcation graft deployment system of Claim 1 or the deployment system of Claim 10.

In short, among other reasons, no advantage would result from combining the intraluminal sheath disclosed in Anderson with the balloon expandable stent in Quiachon. The balloon expandable stent in Quiachon gains no advantage from the inclusion of the intraluminal sheath set forth in Anderson. Accordingly, Applicants submit that there would be no motivation to do so.

In particular, with regard to Claim 1, for the reasons stated herein, one skilled in the art would not be motivated by Anderson, or his or her own knowledge, to modify Quiachon to provide a bifurcated graft deployment system comprising, inter alia, and outer sheath and individual restraints on each of the graft portions, as set forth in Claim 1. Because the graft of Quiachon is balloon expandable and, hence, not self-expandable, Applicants submit that one skilled in the relevant art (endoluminal vascular treatment) would not be motivated to combine and, moreover, could not combine, Anderson's sheath 10 with the system of Quiachon to produce a device as in Claims 1-15 with any reasonable expectation of success. This is underscored by the fact that the restraints in both Quiachon and Anderson are single-piece restraints configured to cover the entire stent/graft. (See Quiachon, Figs. 1, 29, 30, col. 5, lines 16-18, Anderson, Fig. 1, col. 4, lines 64-67).

In contrast with the balloon expandable graft and device in Quiachon (*see* Quiachon, col. 9, line 4-6), the device of Claim 1 has three separate graft restraints – one for each of the main vessel portion, first branch vessel portion, and the second branch vessel portion of the bifurcated graft and Claim 10 has three separate covers – one for each of the main body section, first branch section, and second branch section of the self-expanding bifurcated prosthesis. Because the devices of Claims 1 and 10 are self-expandable, the single full-length sheath of either Quiachon or Anderson would not be operable with the self-expanding bifurcated graft/prosthesis set forth in Claims 1, 10, respectively. In particular, the self-expanding bifurcated graft/prosthesis set forth in Claims 1, 10 could not be properly positioned and/or deployed with only the single sheath restraint of Quiachon or Anderson because, *inter alia*, the first and second branch vessel portions of Claim 1 and the first and second branch sections of Claim 10 would self-expand when released from Quiachon's or Anderson's single restraint and would not, after such self-expansion, be positionable within the respective branch vessels.

Quiachon also discloses a proximal (ipsilateral) capsule 132 “mounted to the distal extremity of the capsule catheter elongate tubular member 131 (*see* Quiachon, col. 14, lines 22-24) and a contralateral capsule 202 “to retain the inferior attachment system 176 secured to the contralateral tubular leg 172 (*see* Quiachon, col. 20, lines 50-52). However, Applicants submit that these capsules are not configured to restrain the self-expanding branch sections of Claims 1-15 and would not, therefore, overcome the failure of Quiachon and Anderson to control the expansion of the individual sections of the self-expanding prostheses in Claims 1-15 so that such prostheses could be positioned after the being released from the lengthwise restraint.

Furthermore, as discussed in greater detail above, neither Quiachon nor Anderson disclose or suggest the three separate graft restraints set forth in Claim 1 or the three separate covers set forth in Claim 10. Therefore, Anderson does not overcome Quiachon's failure to disclose or suggest these components and such components would not have been beneficial to Quiachon's non-self-expanding system or obvious to one of ordinary skill in the art at the time of the invention. For at least these reasons, Applicants submit that Claims 1-15 are not unpatentable over Quiachon in view of Anderson.

Furthermore, Applicants submit that Quiachon does not disclose or suggest a distal tip coupled to the inner core. As shown in Figure 1 of Quiachon, the distal capsule assembly 90 is

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not a tip, since the distal extremity 80 of the balloon catheter shaft protrudes further to the distal end of the catheter than the distal capsule assembly 90.

Applicants further submit that Claims 2-9 and 11-15 define patentable distinctions over the cited references, not only for the reasons stated above with respect to Claims 1 and 10, but also on their own merit.

For the foregoing reasons, Applicants respectfully request the Examiner to also withdraw the rejection of Claims 1-15 and to pass these claims to allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/417,651 ENDOLOG.007C4	ENDOLUMINAL VASCULAR PROSTHESIS	05-03-2006
11/623,679 ENDOLOG.007C5	ENDOLUMINAL VASCULAR PROSTHESIS	01-16-2007
10/119,525 ENDOLOG.014C1	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	04-08-2002
11/417,883 ENDOLOG.014C2	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	05-03-2006
10/706,660 ENDOLOG.028C2	DUAL WIRE PLACEMENT CATHETER	11-12-2003
10/820,455 ENDOLOG.054A	ENDOLUMENAL VASCULAR PROSTHESIS WITH NEOINTIMA INHIBITING POLYMERIC SLEEVE	04-08-2004

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11/104,303 ENDOLOG.056A	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	04-12-2005
11/580,201 ENDOLOG.056CP1	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	10-12-2006
11/522,292 ENDOLOG.067A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	09-15-2006
11/623,022 ENDOLOG.075A	DUAL CONCENTRIC GUIDEWIRE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT	01-12-2007
12/257,149 ENDOLOG.085A	STENT	10-23-2008
11/189,101 ENDOLOG.21CP6C2	BIFURCATION GRAFT DEPOLYMENT CATHETER	07-25-2005
11/417,926 ENDOLOG.21CP7C2	IMPLANTABLE VASCULAR GRAFT	05-03-2006
11/764,715 ENDOLOG.21CP7CC	IMPLANTABLE VASCULAR GRAFT	06-18-2007
10/690,227 ENDOLOG.23DV1C1	SINGLE PUNCTURE BIFURCATION GRAFT DEPLOYMENT SYSTEM	10-21-2003
11/214,427 ENDOLOG.4C3C1	BIFURCATED VASCULAR GRAFT AND METHOD AND APPARATUS FOR DEPOLYING SAME	08-29-2005
12/269,677 ENDOLOG.091A	METHOD AND AGENT FOR IN-SITU STABILIZATION OF VASCULAR TISSUE	11-12-2008
12/101,863 ENDOLOG.093A	BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS	04-11-2008

The Applicants direct the Examiner to these applications to consider whether the subject matter claimed, now or as may be amended in the future, as well as the associated prosecution histories, now or in the future, may be relevant to the patentability of the present application (e.g., for reasons of patentability or obviousness-type double patenting). Applicants believe that the Examiner has access to the applications and associated file histories through the Patent Office (e.g., the IFW system). Accordingly, Applicants have not provided copies of these applications or the associated file histories. Applicants would be happy to provide copies of these applications or the associated file histories, now or in the future, should the Examiner so request.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: _____

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